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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/202,791 | 12/22/1998 | KOUJI MATSUSHIMA | 350292000500 | 3409 |

25225 7590 08/11/2005

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EXAMINER

WARE, DEBORAH K

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1651

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/202,791

Applicant(s)

MATSUSHIMA ET AL.

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16,23-26,28,29,31-41,43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16,23-26,28,29,31-41,43 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 16, 23-26, 28-29, 31-41 and 43-44 are presented for reconsideration on the merits.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on June 14, 2005, was received. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please note that examiner is still awaiting the submission of the missing reference by Applicants.

Response to Amendment

The Amendment and extension of time filed April 6, 2005, have been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 16, 23-26, 28-29, 31-41 and 43-44 remain rejected under 35

U.S.C. 102(a) as being anticipated by newly cited Kenji Yokoi et al for reasons of

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record, last Office action of October 6, 2004, see page 7, note that the reference has a different inventive entity.

Claims are drawn to processes for producing anti-IL-8 antibody and treatment of hypoxemia.

The newly cited cited reference noted above teaches the same. Note the abstract only. Further, the anti-IL-8 antibody treatment almost completely prevented destruction of pulmonay architecture of which destruction of pulmonary artchitecture results in severe hypoxemia.

The claims are identical to the cited disclosure and are therefore, considered to be anticipated by the teachings therein.

Response to Arguments

The argument that the Yokoi reference is not a proper reference and further that the earliest priority date for the instant application is July 26, 1996 and September 22, 1996, respectively, however, the earliest priority dates for these priority documents appear to be June 26, 1996 and October 22, 1996, respectively. Furthermore, Applicants have not filed an English translation as required under 37 CFR 1.55(a)(3) for perfecting a claim to priority under 35 U.S.C. 119(a)-(d). The foreign priority filing date must antedate the reference and be perfected. The filing date of the priority document is not perfected unless applicant has filed a certified priority document in the application (and an English language translation, if the document is not in English) (see 37 CFR 1.55(a)(3)) and the examiner has established that the priority document satisfies the enablement and description requirements of 35 U.S.C. 112, first

paragraph. Therefore, Applicants' arguments are deemed persuasive.

Claim Rejections - 35 USC § 103

Claims 16, 23-26, 28-29, 31-41 and 43-44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Folkesson et al in view of Slotmann, for reasons of record in the last office action of October 6, 2004, see pages 7-9.

Response to Arguments

Applicant's arguments filed April 6, 2005, have been fully considered but they are not persuasive. The argument that Exhibit A demonstrates that neutrophils may not play a role (if any) in indirect injury, and thus, there is no evidence that direct injury and indirect injury are expected to be treated the same is noted. However, exhibit A merely shows ARDS can still occur in different settings without neutrophil infiltration. This exhibit A reference mentions nothing about the cause of ARDS and only studies its effects. IL-8 as evidenced in the cited prior art results in the induction of ARDS and hence causes ARDS.

Therefore, one of skill in the art would expect successful results by the anti-IL-8 antibody treatment of ARDS caused by IL-8. Treatment with anti-IL8 antibody can prevent neutrophil infiltration in lungs if it does occur but it also prevents pulmonary edema along with other symptoms and disease of ARDS of which encompasses indirect lung injury disease, such as hypoxemia. Furthermore, the argument that the cited prior art combination fails to teach each and every element is not persuasive since the cited prior art at least suggests each and every element. Although Folkesson may disclose

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only direct injury one of skill would have expected successful results for treatment of indirect injury because of the mechanism of function of anti-IL-8 antibody upon IL-8.

Anti-IL-8 antibody is well known in the cited prior art to neutralize the effects of IL-8, and since IL-8 is known to induce ARDS, and hence cause indirect lung injury its neutralization would be paramount for treatment of indirect lung injury. Furthermore, IL-8 would have been expected to be produced in indirect lung injury from knowing it is produced in direct lung injury and its method of treatment would have been expected to be the same. Although Exhibit B is noted, it is not deemed persuasive either because it also shows as does the cited prior art the neutralization of IL-8 via treatment with anti IL-8 antibody. The cited prior art combination clearly suggests that anti-IL-8 antibody can treat indirect lung injury and the claims remain *prima facie* obvious.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Deborah K. Ware
July 23, 2005


DAVID M. NAFF
PRIMARY EXAMINER
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